

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY-DOCKET NO.
09/253,317	02/19/99	LAM	1

PAUL B. SIMBOLI  
ALZA CORPORATION  
1900 CHARLESTON ROAD  
BLDG. M10-3  
MOUNTAIN VIEW CA 94043-0802

HM22/1108

FAY, EXAMINER

ART. UNIT  
1814

PAPER NUMBER

11/08/01 14

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/253,317

Applicant(s)  
Lam et al.

Examiner  
Zohreh Fay

Art Unit  
1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Art Unit:

Claims 1-34 are presented for examination.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-34 are rejected under 35 U.S.C. 103 as being unpatentable over Dong et al. (U.S. Patent 5,770,227), Patrick et al. And Ayer et al. (U.S. Patent 5,707,668)

Dong et al. Teach the use of a drug, progesterone in an extended release delivery system of multi layers for hormone replacement therapy. See the entire document. Patrick et al. Teach the use of the claimed compound methylphenidate in an extended release form. See the entire article. Ayer et al. Teaches the use of anti-epileptic drugs in an extended release form. The above reference teaches a core of antiepileptic drug, a semipermeable wall which is a polymer, a wall for pushing the therapeutic composition and an exit in the dosage form for delivering the therapeutic composition. See claims. The above references differs from the claimed invention in releasing the active ingredients in an ascending form.

One skilled in the art would have been motivated to employ the teachings of the above references since they relate to the use of the multi layer drug delivery system as claimed herein and also the use of the claimed compounds in a sustained release formulation. The above references also teach a core, a semipermeable polymeric wall and another wall for pushing the therapeutic composition. To determine the rate of the release is considered to be within the skill

Art Unit:

of the art in the absence of evidence to the contrary. The above references make clear that the claimed multi-layer system of delivery is old and well known. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-34 are properly rejected under 35 U.S.C. 103.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examine Fay whose telephone number is (703) 308-4604.

ZOHREN FAY  
PRIMARY EXAMINER  
GROUP 1200



Z.F.

November 7, 2001